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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1146]

Discussion Paper: "A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals"; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a discussion paper entitled ''A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (discussion paper). This discussion paper is the second step in the agency's consideration of issues related to the use of antimicrobial new animal drugs in food-producing animals. FDA is making the discussion paper available to the public to initiate discussions with the scientific community and other interested parties on the agency's thinking about appropriate underlying concepts to be used to develop microbial safety policies protective of the public health.

DATES: Written comments on the discussion paper should be submitted by (*insert date 90 days after date of publication in the* **Federal Register**).

ADDRESSES: Submit written requests for single copies of the discussion paper to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist the office in processing your requests.

Submit written comments on the discussion paper to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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Comments should be identified with the full title of the discussion paper and the docket number found in brackets in the heading of this document.

See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the discussion paper.

FOR FURTHER INFORMATION CONTACT:

Sharon R. Thompson, Office of the Director (HFV–1), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798.

Margaret A. Miller, Office of New Animal Drug Evaluation (HFV–100), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1620.

Linda R. Tollefson, Office of Surveillance and Compliance (HFV–200), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6644.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 18, 1998 (63 FR 64094), FDA published a notice of availability of a draft guidance entitled ''Guidance for Industry: Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals.'' The release of this draft guidance was the first step in the agency's consideration of issues related to the use of antimicrobial new animal drugs in food-producing animals. The draft guidance lays out the agency's rationale for its current thinking about its authority under the Federal Food, Drug, and Cosmetic Act to consider the human health impact of the microbial effects associated with the use of antimicrobial new animal drugs in food-producing animals. Since the 1970's, and until scientific evidence indicated that a change was necessary, the agency had evaluated the human health impact of the microbial effects of only certain uses of antimicrobial new animal drugs in animal feeds. The draft guidance provides that the agency now believes that sponsors of all antimicrobial new animal drugs intended for use in food-producing animals need to provide information that will allow the agency to evaluate the human health impact

of the microbial effects of the intended uses. In assessing the human health impact of such uses, the draft guidance states that two separate but related factors should be evaluated: (1) The quantity of antimicrobial drug-resistant enteric bacteria formed in the animal's intestinal tract following exposure to the antimicrobial new animal drug (resistance), and (2) changes in the number of enteric bacteria in the animal's intestinal tract that cause human illness (pathogen load).

The discussion paper that is the subject of this notice is the second step of the agency's consideration of these issues. It augments the draft guidance made available in November 1998 by setting out a conceptual risk-based framework for evaluating the microbial safety (relating to human health impact) of antimicrobial new animal drugs intended for use in food-producing animals. FDA is making the discussion paper available to the public in order to initiate discussions with the scientific community and other interested parties on the agency's thinking about appropriate underlying concepts to be used to develop policies that are protective of the public health. The agency is seeking comment from the public in two areas. The first is whether the concepts set out in this document, if implemented, will accomplish the goal of protecting the public health by ensuring that significant human antimicrobial therapies are not lost as a result of use of antimicrobial new animal drugs in food-producing animals, while providing for the safe use of antimicrobials in food-producing animals. The second is to obtain input on important areas of scientific complexity outlined in the discussion paper.

This will not be the only opportunity for public comment on these issues. The agency intends to solicit further public comments at the next meeting of FDA's Veterinary Medicine Advisory Committee in Rockville, MD, which is scheduled to be held on January 25 and 26, 1999. Also, comments regarding the draft guidance entitled ''Guidance for Industry: Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' may be submitted at any time.

II. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the* **Federal Register**), submit to the Dockets Management Branch (address above) written comments regarding this discussion paper. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the discussion paper and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the discussion paper using the World Wide Web (WWW). For WWW access, connect to CVM at ''http://www.fda.gov/cvm''.

Dated: December 30, 1998

December 30, 1998

William K. Hubbard
Associate Commissioner for Policy Coordination

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